

Remarks

Claims 1 and 3-35 were pending in the subject application. By this Amendment, the applicant has amended claims 1, 3-5, 8, 12-14, 21-24, and 31. No new matter has been added by these amendments. Support for the amendments to the claims can be found throughout the subject application including, for example, at page 7, lines 12-14 and page 9, lines 1-2. Accordingly, claims 1 and 3-35 are now before the Examiner for consideration.

The amendments set forth herein should not be interpreted to indicate that the applicant has agreed with, or acquiesced to, the rejections set forth in the outstanding Office Action. The amendments to the claims have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. Favorable consideration of the claims now presented, in view of the remarks and amendment set forth herein, is earnestly solicited.

Claims 1, 3-5, 11-14, 20-25, 28-34, and 35 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,758,836 (Zawacki). The applicant respectfully traverses because Zawacki does not teach or suggest the features of the device of the subject invention.

Zawacki teaches a catheter having a split tip, wherein the first catheter tip is presented through a port within the tube wall of the second catheter. In fact, Zawacki clearly discloses at col. 4, lines 57-59 a slidable inner catheter that protrudes from a port (21) in an outer tube (20) located at the proximal end of the second catheter (24), which results in, what the Zawacki reference self-defines as “a split tip catheter.” Zawacki goes on to state that the port is “a very important feature” because it can dislodge clotting formations on the catheter and enables the desired positioning of the tubes (see, for example, col. 4, lines 12-17). Even assuming one would attempt to insert the first catheter through the entire length of the second catheter in the Zawacki design, it would be impossible to do so. A careful reading and review of the figures of Zawacki shows that the port is a necessary exit for the slidable catheter tip because the second catheter is formed as part of the outer tube (20) by reducing the diameter of the tube portion distal to the port (21). Thus, as stated by Zawacki, at col. 3, lines 34-46, the reduction in diameter to form the second catheter necessitates that the first catheter tip exit from a port opening in the lumen that is situated at a proximal distance from the distal end of the second catheter, where the distal end of the second catheter includes a second

opening. This provides two distinct, separate, non-coaxially situated catheter tips necessarily extending in different directions and a device that comprises three different lumens as stated at col. 1, lines 63-67, and, as shown in the figures.

The subject application clearly describes and illustrates a device that, unlike the Zawacki device, utilizes a first catheter (arterial lumen) whose tip and distal aperture extend from the single aperture at the most distal end of a second catheter (venous lumen). Thus, the device of the subject invention comprises only two lumens wherein one is fully coaxial or collinear with the other along its entire length. Thus, unlike the device of Zawacki, which describes a split tip catheter, the lumens of the device of the subject invention have distal apertures necessarily extending in generally the same direction. Claims 1, 3-5, 13, 14, 21-23, and 31 have been amended to clarify that the device of the subject invention comprises an arterial lumen disposed within the entire length of a venous lumen, such that the aperture of the arterial lumen extends through the single aperture at the most distal end of the venous lumen. Applicant respectfully asserts that these amendments suffice to distinguish the device of the subject application from the Zawacki reference.

With regard to claims 3-5, 12-14, and 21-23, which depend from claim 1 discussed above, the Office Action states that Zawacki discloses a slidable inner lumen that permits the position of the inner lumen aperture to be adjusted relative to the aperture of the second catheter tip. And, that the ability to alter the length of the Zawacki lumens allows them to be adjustable or their positions altered as described and claimed in the subject application. The applicant respectfully disagrees with this assertion. Based on the teachings of Zawacki, which requires the inner lumen aperture to be adjusted through a port located along a proximal portion of the second catheter, it would be impossible to adjust the catheters in any manner such that one is fully coaxial or collinear with the other along its entire length. Regardless of the length of the Zawacki slidable catheter, it must still extend from a port opening proximal to the distal end of the second catheter to ensure the split-tip catheter taught by Zawacki.

With regard to claims 11, 20, 24, 25, 27, 28, 29, applicant respectfully asserts that the limitations presented in these claims with regard to the number and shape of lumens, manufacturing

materials, and the use of reinforcing devices or a hub do not cure the defects of the Zawacki reference as discussed above.

Claim 30 has been canceled in order to expedite prosecution of the subject application.

Claim 31 has also been rejected under 35 U.S.C. §103(a) in view of Zawacki. The Office Action asserts that Zawacki discloses the method claimed by the applicant. Applicant respectfully asserts that the Zawacki reference does not disclose the methods recited in claim 31 as currently amended. The method of claim 31 recites a device comprising a dual-lumen catheter wherein the entire length of the outer, venous, lumen is in coaxial configuration with the inner, arterial, lumen, such that the inner lumen extends from the single aperture at the most distal end of the venous lumen. As discussed in detail above, Zawacki discloses a dual-lumen device where the two catheters are split from each other and cannot be aligned in the fashion described in claim 31 above. For example, the inner lumen of Zawacki extends through a port opening at a proximal end and does not extend through a single aperture at the most distal end of the second catheter, and, as discussed above, could not do so, even if the location of the port is altered, because of the reduction in diameter at the distal end of the second catheter. To do so would destroy the function and intent of the Zawacki catheter.

With regard to the rejection of claims 32, 33, 34, and 35, which depend from claim 31 the Office Action correctly notes that these claims pertain to the use of a guidewire for the placement of the subject device through a large central vein into the superior vena cava and atrium of a patient and to the use of a hub to connect the entire assembly. But, the applicant respectfully asserts, again, that the addition of these limitations does not cure the more serious defects of the Zawacki reference discussed above with regard to amended claim 31.

Therefore, in view of the above remarks and the amendments to the claims, particularly to claim 1, the applicant believes that the subject application and claims are clearly distinguished from the device of Zawacki. Accordingly, reconsideration and withdrawal of the rejection of claims 1, 3-5, 11-14, 20-25, 28-34, and 35 under 35 U.S.C. §103(a) is respectfully requested.

Claims 6-7, 15-16, and 26 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Zawacki in view of Davey *et al.* (U.S. Patent No. 6,595,966). The applicant respectfully

traverses this rejection. The Office Action contends that Zawacki discloses the device of the subject invention with exception of the tapered distal end and use of a therapeutic agent.

Applicant disagrees that Zawacki discloses the device of the subject invention. As discussed in detail above, unlike the subject application, Zawacki discloses a split tip catheter, where one catheter necessary exits from the second catheter through a port located along a proximal portion of the second catheter. The tapering lumens and use of the anticoagulant, heparin, taught by Davey *et al.* do not cure the defects of the Zawacki reference. Accordingly, the applicant respectfully requests reconsideration and withdrawal of the rejection of claims 6-7, 15-16, and 26 under 35 U.S.C. §103(a).

Claims 9, 10, 18, and 19 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Zawacki in view of Klein (U.S. Patent No. 6,758,836). Applicant respectfully traverses. The Office Action again asserts that Zawacki discloses the device of the subject invention except for the ridge and spoke configuration taught by Klein. As discussed above, applicant respectfully reiterates that Zawacki does not teach the device of the herein amended claims. In addition, Applicant respectfully disagrees with the assertion that the “peaks” and “flat regions” described by Klein are analogous to the ridges or spokes disclosed in the subject application. Klein discloses both in the Figures and at column 8, lines 17-24 that these “V”-shaped peaks (col. 8, line 33) produce a “low friction surface” (col. 8, line 16). They are obviously not designed to connect or attach the lumens, as are the spokes and ridges claimed by the subject invention. Thus, the addition of the “V”-shaped peaks of Klein to the device of Zawacki will not cure the other significant defects of the Zawacki reference.

Applicant would like to point out that Klein does disclose, only in Figure 5, a type of catheter having a first circular lumen and second crescent-shaped lumen attached along their length by a third lumen that essentially divides the crescent-shaped lumen. Barring, for now, the fact that the subject application does not disclose ridges or spokes comprising a lumen, the addition this embodiment of Klein or the spokes and/or ridges of the subject invention would fundamentally change the operation of the Zawacki device. As the Office Action points out on page 3, line 2, Zawacki discloses “that the inner lumen is slidable and may extend beyond the distal end of the outer lumen.” Claims 9, 10, 18

and 19 clearly state that the spoke and/or ridges are attached between the inner surface of the outer lumen and the outer surface of the inner lumen. Therefore, the addition of the third lumen disclosed by Klein or the spokes or ridges as claimed in the subject invention would require the lumens of Zawacki to be connected, thus eliminating the slidability of the inner lumen.

In view of the above comments, applicant respectfully requests reconsideration and withdrawal of the rejection of claims 9, 10, 18, and 19 under 35 U.S.C. §103(a).

Finally, claims 8 and 17 have been rejected under 35 U.S.C. §103(a) based on Zawacki in view of Miller *et al.* (U.S. Patent No. 5,683,640). The deficiencies of Zawacki are reasserted here. Miller *et al.* describes dual lumen catheters wherein both lumens terminate at the same or very close to the same point (*i.e.* are of essentially the same length), but neither Zawacki nor Miller *et al.* teach a dual-lumen catheter of the subject invention having an arterial lumen disposed within the entire length of the venous lumen in a co-axial fashion such that the arterial lumen extends through and significantly beyond the most distal point of the venous lumen. Thus, the deficiencies of Zawacki are not cured by the addition of Miller *et al.*

In addition, the Office Action puts forth that it would have been obvious to fuse the lumens disclosed by Zawacki into a single piece, as disclosed by Miller. The applicant respectfully disagrees because, as pointed out above, fusing the lumens of Zawacki would defeat the purpose of the Zawacki device, which is to provide a slidable inner lumen. In fact, Zawacki specifically teaches away from any locking mechanism that would permanently fix the positions of the lumens. The applicant refers to column 7, lines 25-48 where Zawacki states that his disclosed locking mechanisms “remove a design constraint for using materials that will fuse together”, and then goes on to promote the use of dissimilar materials for manufacture of the locking mechanisms to ensure that they do not become permanently fused. Thus, it appears to the applicant that Zawacki would not advocate the use of the Miller design of fused lumens.

In view of these comments, the applicant respectfully requests reconsideration and withdrawal of the rejection of claims 8 and 17 under 35 U.S.C. §103(a).

In view of the foregoing remarks and the amendments above, the applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicant also invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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